UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION
PREVENTION

April 12, 2016

MEMORANDUM

Subject: Efficacy Review for XHC-E, EPA File Symbol 1677-ELU; DB Barcode: D431608.

From: Ibrahim Laniyan, Ph.D.
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Thru: Mark Perry, Team Leader
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Antimicrobials Division (7510P)

Applicant: Ecolab Inc.
370 N. Wabasha Street
St. Paul, MN 55102

Formulation from the Label:

Active Ingredient	% by wt.
**Sodium hypochlorite	3.9 %
Other Ingredient: ***Water	96.1 %
Total	100.0 %

[**Equivalent to 0.55% available chlorine] [***USP Water for Injection]

I. BACKGROUND

The product, XHC-E (EPA File Symbol 1677-ELU) is a new product. The applicant requested to register the product as a disinfectant (bactericide, fungicide, virucide) and a sanitizer for, non-food contact surfaces, hard, non-porous surfaces in clean room environments, industrial areas commercial, animal care, and hospital or medical environments. Studies were conducted at Ecolab, Ecolab Schuman Campus, located at 655 Lone Oak Drive, Eagan, MN 55121-1560; and Accuratus Lab Services, located at 1285 Corporate Center Drive, Suite 110, Eagan, MN 55121.

This data package identified as D431608 contained a letter from the applicant to EPA (dated November 3, 2015), EPA Form 8570-1 (Application for Pesticide), EPA Form 8570-34 (Certification with Respect to Citation of Data), EPA Form 8570-35 (Data Matrix), an Efficacy Discussion Volume, 16 new studies (MRID Nos. 497410-03 through 497410-18), Statements of No Data Confidentiality Claims for each study, and the proposed label (dated October 28, 2015).

II. USE DIRECTIONS

DESINFECTANT: For heavily soiled areas, a pre-cleaning step is required. Apply solution with mop, cloth, [sponge], [brush], [scrubber], disposable wiper, [coarse spray device,] or by soaking so as to wet all surfaces thoroughly. [If applying with a spray device, hold the bottle upright 6-8" from the surface. Always close the nozzle after use.] All surfaces must remain wet for a minimum of 7 minutes and then either allow to air dry or wipe dry with a [sterilized] cloth or wipe.
VIRUCIDAL: All surfaces must remain wet for a minimum of 5 minutes.
FUNGICIDAL: All surfaces must remain wet for a minimum of 5 minutes.

SANITIZATION: Allow surfaces to remain wet for a minimum of 3 minutes and then either allow to air dry or if desired wipe dry with a [sterilized] cloth or wiper.

DIRECTIONS FOR USE AS A STERILANT: Use only on hard, non-porous surfaces. Remove any obvious debris or organic material from the surface to be cleaned. Apply ready to use solution by immersion of objects in containers by covering interior surfaces of containers, or by confining (e.g. rimmed) surfaces (e.g. floors, tables, counters) that permit a continuous layer of liquid to cover the surface for the recommended contact time of 5 hours. This product is effective against *Clostridium sporogenes (*ATCC 3584*)* and *Bacillus subtilis (*ATCC 19659*)* [with a 5% organic soil load]. Remove used solution and entrapped soil with a clean, dry, sterile cloth. Do not use this product as a sterilant on medical devices.

DIRECTIONS FOR USE AS A SPORICIDE: This product kills and/or inactivates spores of *Clostridium difficile* (ATCC 43598) on hard, non-porous surfaces. This product is effective against *Clostridium difficile* spores after a 10 minute exposure time.

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Surface Sporocides: The AOAC Sporicidal Test is required for substantiating sterilizing claims. The following information applies to all products represented as sporicidal or sterilizing agents. Sixty carriers, representing the type of surfaces (porous or non-porous), must be tested against spores of both *Bacillus subtilis* (ATCC 19659) and *Clostridium sporogenes* (ATCC 3584) on 3 product samples representing 3 different batches, at LCL (120 carriers per sample; a total of 360 carriers). Any sterilizing agent (liquid, vapor, or gas) that is recommended for use in a specific device must be tested by the AOAC Sporicidal Test in that specific device and according to the directions for use. **Performance Standard:** Killing on all of the 360 carriers is required; no failures are permitted. Data to support sterilizing claims must be confirmed by tests conducted by a second, independent laboratory of the applicant's choice (other than the laboratory that developed the original data). The following minimal confirmatory data must be developed on one sample of the product: Thirty carriers of the type of surfaces (porous

or non-porous) against spores of both *Bacillus subtilis* and *Clostridium sporogenes* (a total of 60 carriers) by the AOAC Sporicidal Test.

Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments: The effectiveness of disinfectants for use on hard surfaces in hospital or medical environments must be substantiated by data derived using the AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products Test (for spray products), or the AOAC Hard Surface Carrier Test. The tests require that sixty carriers must be tested with each of 3 samples, representing 3 different product lots at the LCL, against *Staphylococcus aureus* ATCC 6538 (for effectiveness against Gram-positive bacteria), and *Pseudomonas aeruginosa* ATCC 15442 (representative of a nosocomial pathogen), [120 carriers per sample; a total of 360 carriers]. To support products labeled as "disinfectants", killing on 59 out of 60 carriers is required in AOAC Germicidal Spray Products Test to provide effectiveness at the 95% confidence level. To pass performance requirements when using AOAC Hard Surface Carrier Test, tests must result in killing in 58 out of each set of 60 carriers for *Staphylococcus aureus* ATCC 6538; 57 out of each set of 60 carriers for *Pseudomonas aeruginosa* ATCC 15442. Performance requirements when using AOAC Use-Dilution Method are killing in 57 out of each set of 60 carriers for *Staphylococcus aureus* ATCC 6538 and 54 out of each set of 60 carriers for *Pseudomonas aeruginosa* ATCC 15442. Each microbe should be tested three times. Each test should be conducted against a separate batch of product for a total of three batches. Each of the three tests should be conducted on a different day.

Disinfectant With sporicidal activity against *Clostridium difficile:* The Agency has established interim guidance for the efficacy evaluation of antimicrobial products (e.g., dilutable products, ready-to-use products, spray products, vapor, gases, and towelettes) that are labeled for use to treat hard, non-porous surfaces in healthcare settings contaminated with spores of *Clostridium difficile*. The effectiveness of such a product must be substantiated by data derived from ASTM E 2197: Standard Quantitative Carrier Test Method to Evaluate the Bactericidal, Fungicidal, Mycobactericidal, and Sporicidal Potencies of Liquid Chemical Germicides. Modifications to each test method will be necessary to specifically accommodate spores of *Clostridium difficile*. Because *Clostridium difficile* is an obligate anaerobe, testing should ensure adequate incubation conditions for the recovery of viable spores. Three product batches should be tested at the lower certified limit(s) (LCL) listed on the confidential statement of formula (CSF) of the product. The toxigenic strains, ATCC 43598, of *Clostridium difficile* must be used for testing. For towelette and spray formulations, the Agency will accept testing of the liquid expressed directly from towelettes or collected directly from spray containers using one of the quantitative methods and conditions specified above. All products should be tested with a 3-part soil load incorporated into the test inoculum by adding 25 µl of 5% bovine serum albumin, 35 µl of 5% yeast extract and 100 µl of 0.4% mucin to 340 µl of the spore suspension. Results must show a minimum 6 log reduction of viable spores in 10 minutes or less. For towelette products, wetness determination test will be used to generate the contact time. Control carrier counts must be greater than 10^6 spores/carrier. The titer and purity of the final spore preparation must be $>10^8$ spores/mL, and >95% spores. ASTM Standard E2839 specifies procedures for achieving the 95% purity. The acid resistance of purified spores should be assessed against 2.5 M hydrochloric acid (see ASTM Standard E2839). The spores are considered acid-resistant if a log reduction of 0-2 is exhibited following 10 minutes of exposure to 2.5 M HCl.

Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments (Additional Bacteria): Effectiveness of disinfectants against specific bacteria other than those named in the AOAC Use- Dilution Method, AOAC Germicidal Spray Products as Disinfectants Method, AOAC Fungicidal Test, and AOAC Tuberculocidal Activity Method, must be determined by either the AOAC Use-Dilution Method or the AOAC Germicidal Spray Products as Disinfectants Method. Ten carriers must be tested against each specific microorganism with each of 2 product samples, representing 2 different product lots at LCL. To support products labeled as "disinfectants" for specific bacteria (other than those bacteria named in the above test methods), killing of the specific microorganism on all carriers is required.

Disinfectants for Use as Fungicides (Against Pathogenic Fungi, Using a Modified Method): The effectiveness of liquid disinfectants against specific pathogenic fungi must be supported by efficacy data using an appropriate test. The AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray or towelette products) may be modified to conform to appropriate elements in the AOAC Fungicidal Test. The inoculum in the test must be modified to provide a concentration of at least 10^6 conidia per carrier. Ten carriers on each of 2 product samples representing 2 different product lots at LCL must be employed in the test. Killing of the specific pathogenic fungi on all carriers is required.

Virucides: The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots of disinfectant at LCL must be tested against a recoverable virus titer of at least 10^4 from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level.

Supplemental Claims: An antimicrobial agent identified as a "one-step" disinfectant or as effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5% serum.

IV. BRIEF DESCRIPTION OF THE DATA

1. MRID 497410-03 "XHC-E Hospital Disinfection Efficacy, Test Organisms: *Staphylococcus aureus* (ATCC 6538) and *Pseudomonas aeruginosa* (ATCC 1544)", by Lisa Hellickson. Study conducted at Ecolab. Study completion date – June 25, 2015. Project Number 1500023.

This study was conducted against *Staphylococcus aureus* (ATCC 6538) and *Pseudomonas aeruginosa* (ATCC 1544). Three lots (Lot Nos. 3483SWE105, 3503SWB105, and 4443SWB105) of the product, XHC-E, were tested according to Ecolab Microbiological Services SOP MS003-30; *Use Dilution Method* and SOP MS003-31. The product was RTU but product lots tested were diluted so that the active ingredient level is at or below the lower limit of 5000 ppm available chlorine. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Sixty (60) stainless steel penicylinder carriers were immersed in a 48-54 hour old suspension of the test organism, at a ratio of 1 carrier per 1.0 ml broth. The carriers were dried for 40±2 minutes at 35±2°C. Each carrier was exposed to 10 ml of the use solution for 7 minutes at 20±1°C. After exposure, the carriers were transferred to 10 ml of Letheen Broth containing 0.5% Sodium Thiosulfate to neutralize. All subcultures were incubated for 48±2 hours at 35±2°C. Some of the subcultures were stored at 2-8°C prior to examination. Following incubation and storage, the subcultures were examined for the presence or absence of visible growth. The positive tubes were confirmed for the presence of the test system by subculturing to Tryptic Soy Agar (TSA). The positive tubes were also Gram stained (stains from all positive tubes matched the test system). The plates were examined for typical colony morphology and Gram stain. The identification of the growth from the positive tube was confirmed using the Vitek 2 Compact identification system. Pseudomonas Isolation Agar (PIA) was used to confirm the Vitek 2 Compact results for the *Pseudomonas aeruginosa* positive from batch 3483SWE105. All plates were incubated at 35 ± 2°C for 18- 24 hours. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

Note: One protocol amendments were reviewed.

2. MRID 497410-04 "Fungicidal Use-Dilution Method, Test Organisms: *Trichophyton mentagrophytes* (ATCC 9533), for XHC-E, by Jamie Herzan. Study conducted at Accuratus Lab Services. Study completion date – July 7, 2015. Project Number A18343.

This study was conducted against *Trichophyton mentagrophytes* (ATCC 9533). Two lots (Lot Nos. 3483SWE105 and 3503SWB105) of the product, XHC-E, were tested according to Accuratus Lab protocol EC001040915.FUD.1 (copy provided). The product was RTU but product lots tested were diluted so that the active ingredient level is at or below the lower limit of 5000 ppm available chlorine. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) stainless steel penicylinder carriers were immersed for 15±2 minutes in a prepared suspension at a ratio of one carrier per one ml of culture. The carriers were dried for 40±2 minutes at 36±1°C and 53-54% RH. Each carrier was exposed to 10 ml of the use solution for 5 minutes at 19-20°C. After exposure, the carriers were transferred to 10 ml of Sabouraud Dextrose Broth + 0.07% Lecithin + 0.5% Tween 80 to neutralize and subculture. All neutralized subcultures were incubated for 10 days at 25-30°C. The agar plate subcultures were incubated for 44-76 hours at 25-30°C. Following incubation, the subcultures were visually examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

Note: One protocol amendment was reviewed.

3. MRID 497410-05 "Fungicidal Use-Dilution Method, Test Organisms: *Aspergillus brasiliensis* (ATCC 16404), for XHC-E, by Matthew Sathe. Study conducted at Accuratus Lab Services. Study completion date – June 25, 2015. Project Number A18370.

This study was conducted against *Aspergillus brasiliensis* (ATCC 16404). Two lots (Lot Nos. 3483SWE105 and 3503SWB105) of the product, XHC-E, were tested according to Accuratus Lab protocol ECO01040915.FUD.2 (copy provided). The product was RTU but product lots tested were diluted so that the active ingredient level is at or below the lower limit of 5000 ppm available chlorine. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) stainless steel penicylinder carriers were immersed for 15±2 minutes in a prepared suspension at a ratio of one carrier per one ml of culture. The carriers were dried for 38 minutes at 36.3°C and 53% RH. Each carrier was exposed to 10 ml of the use solution for 5 minutes at 21°C. After exposure, the carriers were transferred to 10 ml of Sabouraud Dextrose Broth + 0.07% Lecithin + 0.5% Tween 80 to neutralize and subculture. All neutralized subcultures were incubated for 10 days at 25-30°C. The agar plate subcultures were incubated for 44-76 hours at 25-30°C. Following incubation, the subcultures were visually examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

4. MRID 497410-06 "Fungicidal Use-Dilution Method, Test Organisms: *Candida albicans* (ATCC 10231), for XHC-E, by Matthew Sathe. Study conducted at Accuratus Lab Services. Study completion date – June 30, 2015. Project Number A18371.

This study was conducted against *Candida albicans* (ATCC 10231). Two lots (Lot Nos. 3483SWE105 and 3503SWB105) of the product, XHC-E, were tested according to Accuratus Lab protocol ECO01040915.FUD.3 (copy provided). The product was RTU but product lots tested were diluted so that the active ingredient level is at or below the lower limit of 5000 ppm available chlorine. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) stainless steel penicylinder carriers were immersed for 15±2 minutes in a prepared suspension at a ratio of one carrier per one ml of culture. The carriers were dried for 38 minutes at 36.3°C and 55.4% RH. Each carrier was exposed to 10 ml of the use solution for 5 minutes at 19°C. After exposure, the carriers were transferred to 10 ml of Sabouraud Dextrose Broth + 0.07% Lecithin + 0.5% Tween 80 to neutralize and subculture. All neutralized subcultures were incubated for 48±2 hours at 25-30°C. Following incubation, the subcultures were visually examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

5. MRID 497410-07 "Sporicidal Activity of Disinfectants on Hard Surfaces, Test Organisms: *Bacillus subtilis* (ATCC 19659) and *Clostridium sporogenes* (ATCC 3584), for XHC-E, by Matthew Sathe. Study conducted at Accuratus Lab Services. Study completion date – September 2, 2015. Project Number A18372.

This study was conducted against *Bacillus subtilis* (ATCC 19659) and *Clostridium sporogenes* (ATCC 3584). Three lots (Lot Nos. 3483SWE105, 3503SWB105, and 4443SWB105) of the product, XHC-E, were tested according to Accuratus Lab protocol ECO01040915.SPOR.1 (copy provided). The product was RTU but product lots tested were diluted so that the active ingredient level is at or below the lower limit of 5000 ppm available chlorine. Fetal bovine serum was added to the spore suspension to achieve a 5% organic soil load. Sixty (60) stainless steel penicylinder carriers were contaminated by immersion in ≥95% spores suspension of a 72±2 hour old culture of the test organism, at a ratio of 1 carrier per 1 ml of broth. The carriers were vacuum-dried at ≥69 cm Hg for at least 22 hours. Five dried carriers were placed in tubes and exposed to 10.0 ml of the use solution for 5 hours (300 min.) at 20±1°C. After the contact period, each carrier was transferred to individual tubes containing 10 ml of Fluid Thioglycollate Medium for primary neutralization subculturing. After one hour, the carriers were transferred to secondary subculture tubes containing Fluid Thioglycollate Medium. The subcultures were incubated for 21 days at 35-37°C, and then examined for growth. Tubes showing no growth were heat-shocked for 20 minutes at 80±2°C, re-incubated for 72±2 hours at 35-37°C, and again examined for growth. Controls included those for purity, sterility, viability, carrier population count, neutralization confirmation, and acid resistance at 2, 5, 10, and 20 minutes.

6. MRID 497410-08 "Sporicidal Activity of Disinfectants on Hard Surfaces, Test Organisms: *Bacillus subtilis* (ATCC 19659) and *Clostridium sporogenes* (ATCC 3584), for XHC-E, by Joshua Luedtke. Study conducted at Accuratus Lab Services. Study completion date – July 21, 2015. Project Number A18391.

This study was conducted against *Bacillus subtilis* (ATCC 19659) and *Clostridium sporogenes* (ATCC 3584). One lot (3503SWB105) of the product, XHC-E, was tested according to Accuratus Lab protocol ECO01040915.SPOR.2 (copy provided). The product was RTU but product lots tested were diluted so that the active ingredient level is at or below the lower limit of 5000 ppm available chlorine. Fetal bovine serum was added to the spore suspension to achieve a 5% organic soil load. Thirty (30) stainless steel penicylinder carriers were contaminated by immersion in ≥95% spores suspension of a 72±2 hour old culture of the test organism, at a ratio of 1 carrier per 1 ml of broth. The carriers were vacuum-dried at ≥69 cm Hg for at least 22 hours. Five dried carriers were placed in tubes and exposed to 10.0 ml of the use solution for 5 hours (300 min.) at 20±1°C. After the contact period, each carrier was transferred to individual tubes containing 10 ml of Fluid Thioglycollate Medium for primary neutralization subculturing. After one hour, the carriers were transferred to secondary subculture tubes containing Fluid Thioglycollate Medium. The subcultures were incubated for 21 days at 35-37°C, and then examined for growth. Tubes showing no growth were heat-shocked for 20 minutes at 80±2°C, re-incubated for 72±2 hours at 35-37°C, and again examined for growth. Controls included those for purity, sterility, viability, carrier population count, neutralization confirmation, and acid resistance at 2, 5, 10, and 20 minutes.

7. MRID 497410-09 "Standard Quantitative Disk Carrier Test Method, Test Organisms: *Clostridium difficile* - spore form (ATCC 43598), for XHC-E, by Joshua Luedtke. Study conducted at Accuratus Lab Services. Study completion date – July 16, 2015. Project Number A18392.

This study was conducted against *Clostridium difficile* (spore form) (ATCC 43598). Three lots (Lot Nos. 3483SWE105, 3503SWB105, and 4443SWB105) of the product, XHC-E, were tested according to Accuratus Lab protocol ECO01040915.QDCT (copy provided). The product was RTU but product lots tested were diluted so that the active ingredient level is at or below the lower limit of 5000 ppm available chlorine. The product was tested in the presence of 0.25% Bovine Serum Albumin, 0.08% Bovine Mucin and 0.35% Yeast Extract. Twenty (20) brushed stainless steel (AISI #430) disk carriers (1 cm diameter, 0.7 mm thick) per product lot were

inoculated with 10 µL of a 10-day old culture of 98% pure test organism. The carriers were dried in a biosafety hood for 30±5 minutes with the Petri dish lid off; then in a vacuum desiccator for 2 hours at 21°C. Each carrier was transferred, inoculated side up, to a QCT vial, to which 50 µL of the use solution was added. The carriers remained exposed to the use solution for 10 minutes at 20-21°C and 26-46% relative humidity. Following exposure, 10.0 mL of PBS + 0.1% Tween 80 + 0.5% Sodium Thiosulfate was added to each vial to neutralize. The contents of each vial were vortex mixed for 30 seconds. The entire mixture was filter through an individual 0.2 µm porosity membrane filter. Each vial was rinsed with saline four times, with each rinse poured through the same membrane filter. Each membrane filter was plated on BHI-HT Agar and incubated anaerobically for 120±4 hours (5 days) at 35-37°C. Following incubation. Following incubation, the subcultures were examined for the presence or absence of visible growth and the number of survivors was enumerated. Controls included those for initial suspension count, carrier population, purity, sterility, neutralization confirmation, and acid resistance.

8. MRID 497410-10 "AOAC Use-Dilution Method, Test Organisms: *Escherichia coli* (ATCC 11229)", by Jamie Herzan. Study conducted at Accuratus Lab Services. Study completion date – May 21, 2015. Project Number A18348.

This study was conducted against *Escherichia coli* (ATCC 11229). Two lots (Lot Nos. 3483SWE105 and 3503SWB105) of the product, XHC-E, were tested according to Accuratus Lab protocol ECO01040915. UD (copy provided). The product was RTU but product lots tested were diluted so that the active ingredient level is at or below the lower limit of 5000 ppm available chlorine. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) stainless steel penicylinder carriers per lot were immersed in a 48-54 hour old suspension of the test organism, at a ratio of 1 carrier per 1.0 ml broth. The carriers were dried for 38 minutes at 36.1°C. Each carrier was exposed to 10 ml of the use solution for 5 minutes at 20±1°C. After exposure, the carriers were transferred to 10 ml of Letheen Broth + 0.5% Sodium Thiosulfate to neutralize and subculture. All subcultures were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

9. MRID 497410-11 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Test Organisms: Adenovirus type 5 (ATCC VR-5, Strain Adenoid 75)", by Mary J. Miller. Study conducted at Accuratus Lab Services. Study completion date – June 4, 2015. Project Number A18341.

This study was conducted against Adenovirus type 5 (ATCC VR-5, Strain Adenoid 75), using A-549 cells (human lung carcinoma, ATCC CCL-185; propagated in-house) as the host system. Two lots (Lot Nos. 3483SWE105 and 3503SWB105) of the product, XHC-E, were tested according to Accuratus Lab protocol ECO01040915.ADV (copy provided). The product was RTU but product lots tested were diluted so that the active ingredient level is at or below the lower limit of 5000 ppm available chlorine. The stock virus culture was adjusted to contain a 5% organic soil load (fetal bovine serum). Films of virus were prepared by spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried at 20.0°C for 20 minutes at 40% relative humidity. For each lot of product, separate dried virus films were individually exposed to a 2.00 mL aliquot of the use dilution of the test substance. The virus films were completely covered with the use solution, and remained exposed to the use solution for 5 minutes at 20.0°C. After exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixture was passed through a Sephadex column, and diluted serially in Minimum Essential Medium supplemented with 5% (v/v) heat-inactivated fetal bovine serum, 10 µg/ml gentamicin, 100 units/ml penicillin, and 2.5 µg/ml amphotericin B. A-549 cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 ml of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2 and scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for cytotoxicity, dried virus count, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. The titer of the dried virus control was **8.0 $\log_{10}$**. Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was **≥7.5 $\log_{10}$** for both batches.

10. MRID 497410-12 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental

Surfaces, Test Organisms: Herpes simplex virus type 1 (ATCC VR-733, Strain F(1))", by Mary J. Miller. Study conducted at Accuratus Lab Services. Study completion date – June 4, 2015. Project Number A18345.

This study was conducted against Herpes simplex virus type 1 (ATCC VR-733, Strain F(1)), using Vero cells (ATCC CCL-81; propagated in-house) as the host system. Two lots (Lot Nos. 3483SWE105 and 3503SWB105) of the product, XHC-E, were tested according to Accuratus Lab protocol ECO01040915.HSV1 (copy provided). The product was RTU but product lots tested were diluted so that the active ingredient level is at or below the lower limit of 5000 ppm available chlorine. The stock virus culture was adjusted to contain a 5% organic soil load (fetal bovine serum). Films of virus were prepared by spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried at 20.0°C for 20 minutes at 40% relative humidity. For each lot of product, separate dried virus films were individually exposed to a 2.00 mL aliquot of the use dilution of the test substance. The virus films were completely covered with the use solution, and remained exposed to the use solution for 5 minutes at 20.0°C. After exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixture was passed through a Sephadex column, and diluted serially in Minimum Essential Medium supplemented with 5% (v/v) heat-inactivated fetal bovine serum, 10 µg/ml gentamicin, 100 units/ml penicillin, and 2.5 µg/ml amphotericin B. Vero cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 ml of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2 and scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for cytotoxicity, dried virus count, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. The titer of the dried virus control was **6.0 $\log_{10}$**. Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was **≥5.5 $\log_{10}$** for both batches.

11. MRID 497410-13 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Test Organisms: Rhinovirus type 37 (ATCC VR-1147, Strain 151-1)", by Mary J. Miller. Study conducted at Accuratus Lab Services. Study completion date – June 4, 2015. Project Number A18347.

This study was conducted against Rhinovirus type 37 (ATCC VR-1147, Strain 151-1), using MRC-5 cells (human embryonic lung, ATCC CCL-171; propagated in-house) as the host system. Two lots (Lot Nos. 3483SWE105 and 3503SWB105) of the product, XHC-E, were tested according to Accuratus Lab protocol ECO01040915.R37 (copy provided). The product was RTU but product lots tested were diluted so that the active ingredient level is at or below the lower limit of 5000 ppm available chlorine. The stock virus culture was adjusted to contain a 5% organic soil load (fetal bovine serum). Films of virus were prepared by spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried at 15.5°C for 20 minutes at 55% relative humidity. For each lot of product, separate dried virus films were individually exposed to a 2.00 mL aliquot of the use dilution of the test substance. The virus films were completely covered with the use solution, and remained exposed to the use solution for 5 minutes at 20.0°C. After exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixture was passed through a Sephadex column, and diluted serially in Minimum Essential Medium supplemented with 5% (v/v) heat-inactivated fetal bovine serum, 10 µg/ml gentamicin, 100 units/ml penicillin, and 2.5 µg/ml amphotericin B. MRC-5 cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 ml of the dilutions. The cultures were incubated at 31-35°C in a humidified atmosphere of 5-7% CO_2 and scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for cytotoxicity, dried virus count, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. The titer of the dried virus control was **5.75 $\log_{10}$**. Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was **≥5.25 $\log_{10}$** for both batches.

12. MRID 497410-14 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Test Organisms: Influenza A virus (ATCC VR-544, Strain Hong Kong)", by Mary J. Miller. Study conducted at Accuratus Lab Services. Study completion date – June 10, 2015. Project Number A18342.

This study was conducted against Influenza A virus (ATCC VR-544, Strain Hong Kong), using MDCK cells (canine kidney cell, ATCC CCL-34; propagated in-house) as the host system. Two lots (Lot Nos. 3483SWE105 and 3503SWB105) of the product, XHC-E, were tested according to Accuratus Lab protocol ECO01040915.FLUA (copy provided). The product was RTU but product lots tested were diluted so that the active ingredient level is at or below the lower limit of 5000 ppm available chlorine. The stock virus culture was adjusted to contain a 5% organic soil load (fetal bovine serum). Films of virus were prepared by spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried at 20.0°C for 20 minutes at 40% relative humidity. For each lot of product, separate dried virus films were individually exposed to a 2.00 mL aliquot of the use dilution of the test substance. The virus films were completely covered with the use solution, and remained exposed to the use solution for 5 minutes at 20.0°C. After exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixture was passed through a Sephadex column, and diluted serially in Minimum Essential Medium supplemented with 2µg/ml TPCK-trypsin, 25 mM HEPES, 0.2% bovine serum albumin (BSA) fraction V, 10 µg/ml gentamicin, 100 units/ml penicillin, and 2.5 µg/ml amphotericin B. MDCK cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 ml of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2 and scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for cytotoxicity, dried virus count, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. The titer of the dried virus control was **5.25 $\log_{10}$**. Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was **≥4.75 $\log_{10}$** for both batches.

13. MRID 497410-15 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Test Organisms: Herpes simplex virus type 2 (ATCC VR-734, Strain G)", by Mary J. Miller. Study conducted at Accuratus Lab Services. Study completion date – June 4, 2015. Project Number A18346.

This study was conducted against Herpes simplex virus type 2 (ATCC VR-734, Strain G), using Vero cells (ATCC CCL-81; propagated in-house) as the host system. Two lots (Lot Nos. 3483SWE105 and 3503SWB105) of the product, XHC-E, were tested according to Accuratus Lab protocol ECO01040915.HSV2 (copy provided). The product was RTU but product lots tested were diluted so that the active ingredient level is at or below the lower limit of 5000 ppm available chlorine. The stock virus culture was adjusted to contain a 5% organic soil load (fetal bovine serum). Films of virus were prepared by spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried at 20.0°C for 20 minutes at 40% relative humidity. For each lot of product, separate dried virus films were individually exposed to a 2.00 mL aliquot of the use dilution of the test substance. The virus films were completely covered with the use solution, and remained exposed to the use solution for 5 minutes at 20.0°C. After exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixture was passed through a Sephadex column, and diluted serially in Minimum Essential Medium supplemented with 5% (v/v) heat-inactivated fetal bovine serum, 10 µg/ml gentamicin, 100 units/ml penicillin, and 2.5 µg/ml amphotericin B. Vero cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 ml of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2 and scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for cytotoxicity, dried virus count, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. The titer of the dried virus control was **5.50 $\log_{10}$**. Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was **≥5.0 $\log_{10}$** for both batches.

14. MRID 497410-16 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Test Organisms: Herpes simplex virus type 2 (ATCC VR-734, Strain G)", by Shanen Conway. Study conducted at Accuratus Lab Services. Study completion date – July 6, 2015. Project Number A18364.

This study was conducted against Poliovirus type 1 (ATCC VR-1562, Strain Chat), using Vero cells (ATCC CCL-81; propagated in-house) as the host system. Three lots (Lot Nos. 3483SWE105 and 3503SWB105, and 4443SWB105) of the product, XHC-E, were tested according to Accuratus Lab protocol ECO01040915.POL

(copy provided). The product was RTU but product lots tested were diluted so that the active ingredient level is at or below the lower limit of 5000 ppm available chlorine. The stock virus culture was adjusted to contain a 5% organic soil load (fetal bovine serum). Films of virus were prepared by spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried at 15.5°C for 20 minutes at 55% relative humidity. For each lot of product, separate dried virus films were individually exposed to a 2.00 mL aliquot of the use dilution of the test substance. The virus films were completely covered with the use solution, and remained exposed to the use solution for 5 minutes at 21.0°C. After exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixture was passed through a Sephadex column, and diluted serially in Minimum Essential Medium supplemented with 5% (v/v) heat-inactivated fetal bovine serum, 10 µg/ml gentamicin, 100 units/ml penicillin, and 2.5 µg/ml amphotericin B. Vero cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 ml of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2 and scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for cytotoxicity, dried virus count, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. The titer of the dried virus control was **6.25 $\log_{10}$**. Taking the cytotoxicity and neutralization control results into consideration, the reduction in viral titer was **≥5.75 $\log_{10}$** for all three batches.

15. MRID 497410-17 "Fungicidal Use-Dilution Method, Test Organisms: *Penicillium chrysogenum* (ATCC 10003), for XHC-E, by Jamie Herzan. Study conducted at Accuratus Lab Services. Study completion date – June 17, 2015. Project Number A18444.

his study was conducted against *Penicillium chrysogenum* (ATCC 10003). Two lots (Lot Nos. 3483SWE105 and 3503SWB105) of the product, XHC-E, were tested according to Accuratus Lab protocol ECO01051215.FUD (copy provided). The product was RTU but product lots tested were diluted so that the active ingredient level is at or below the lower limit of 5000 ppm available chlorine. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) stainless steel penicylinder carriers were immersed for 15±2 minutes in a prepared suspension at a ratio of one carrier per one ml of culture. The carriers were dried for 38 minutes at 36.1-36.3°C and 51.6% RH. Each carrier was exposed to 10 ml of the use solution for 5 minutes at 19°C. After exposure, the carriers were transferred to 10 ml of Sabouraud Dextrose Broth + 0.07% Lecithin + 0.5% Tween 80 to neutralize and subculture. All neutralized subcultures were incubated for 10 days at 25-30°C. The agar plate subcultures were incubated for 44-76 hours at 25-30°C. Following incubation, the subcultures were visually examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

Note: One protocol deviation was reviewed.

16. MRID 497410-18 "XHC-E Non-Food Contact Sanitizing Efficacy, Test Organisms: *Staphylococcus aureus* (ATCC 6538) and *Enterobacter aerogenes* (ATCC 13048)", by Laurinda Holen. Study conducted at Ecolab. Study completion date – May 28, 2015. Project Number 1500032.

This study was conducted against *Staphylococcus aureus* (ATCC 6538) and *Enterobacter aerogenes* (ATCC 13048). Three lots (Lot Nos. 3483SWE105 and 3503SWB105, and 4443SWB105) of the product, XHC-E, were tested according to Ecolab Microbiological Services SOP MS016-27; *Non-Food Contact Sanitizer Test Method.* This method was created from ASTM E1153-14 Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Hard, Nonporous Non-Food Contact Surfaces. The product was RTU but product lots tested were diluted so that the active ingredient level is at or below the lower limit of 5000 ppm available chlorine. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Five sterile stainless steel test squares (1" x 1") carriers per product lot per organism were inoculated with 0.02 ml of a 48±4 hour old suspension of the test organism. The carriers were dried with the petri dish lids slightly ajar in a desiccator containing 86.5% glycerin in a 35±2°C incubator for 20-40 minutes. Each carrier was transferred to a sterile jar and was exposed to 5.0 ml of the use solution at 15-30°C for 3 minutes. After exposure, 20 ml of DE Broth was added to each jar and the jars were rotated vigorously to suspend the surviving organisms. Within 30 minutes of

the addition of the neutralizer, 1.0 ml aliquots of the 10^0 and 10^{-1} dilutions were plated in duplicate on tryptic soy agar. All plates were incubated for 48±4 hours at 30±2°C (*Enterobacter aerogenes*) and 35±2°C (*Staphylococcus aureus*). All test and control plates were stored for 2 days at 2-8°C after incubation before being read. Following incubation and storage, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier quantitation, inoculum count, viability, neutralization confirmation, sterility, and purity. The reported average colony forming units (CFU) per control carrier, for each test microorganism, are as follows: ***Enterobacter aerogenes* 6.2 x 10^6, *Staphylococcus aureus* 1.4 x 10^7**.

V. RESULTS

MRID Number	Organism	Contact Time / Carrier Type	No. Exhibiting Growth/Total No. Tested			Dried Carrier Count (Log_{10} or CFU/ carrier)
			Lot No. 3483SWE 105	Lot No. 3503SWB 105	Lot No. 4443SWB 105	
497410-03	*Pseudomonas aeruginosa*	7 minutes	1/60	1/60	0/60	6.38
	Staphylococcus aureus		1/60	0/60	0/60	6.203
497410-04	*Trichophyton mentagrophytes*	5 minutes	0/10	0/10	-	4.91
497410-05	*Aspergillus brasiliensis*	5 minutes	0/10	0/10	-	5.75
497410-06	*Candida albicans*	5 minutes	0/10	0/10	-	6.09
497410-07	*Bacillus subtilis*	300 min. (5 hours) Stainless Steel	1° = 0/60 2° = 0/60	1° = 0/60 2° = 0/60	1° = 0/60 2° = 0/60	8.5 X 10^5
	Clostridium sporogenes		1° = 0/60 2° = 0/60	1° = 0/60 2° = 0/60	1° = 0/60 2° = 0/60	6.7x10^5
497410-08	*Bacillus subtilis*	300 min. (5 hours) Stainless Steel	-	1° = 0/30 2° = 0/30	-	1.20 X 10^5
	Clostridium sporogenes		-	1° = 0/30 2° = 0/30	-	2.18 x10^5
497410-10	*Escherichia coli*	5 minutes	0/10	0/10	-	6.76
497410-17	*Penicillium chrysogenum*	5 minutes	0/10	0/10	-	6.76

MRID Number	Organism	Lot No. 10-Minute	Average No. Surviving	Spores Initially Present	Percent Reduction
497410-09	*Clostridium difficile* (spore form)	3483SWE105	<1.0	2.63 x 10^6	>99.9999
		3503SWB105	<1.0	2.04 x 10^6	>99.9999
		4443SWB105	<2.7	3.02 x 10^6	>99.9999

MRID Number	Organism	Description 5 minutes	Lot No. 3483SWE105	Lot No. 3503SWB105	Dried Virus Control
497410-11	Adenovirus type 5 (ATCC VR-5, Strain Adenoid 75)	10^{-1} to 10^{-9} dilutions	Complete Inactivation	Complete Inactivation	$10^{8.0}$
		$TCID_{50}$/0.1mL	≤0.50	≤.0.50	
		Log_{10} Reduction	≥7.50	≥7.50	
497410-12	Herpes simplex virus type 1 (ATCC VR-733, Strain F(1))	10^{-1} to 10^{-6} dilutions	Complete Inactivation	Complete Inactivation	$10^{6.0}$
		$TCID_{50}$/0.1mL	≤0.50	≤0.50	
		Log_{10} Reduction	≥5.50	≥5.50	
497410-13	Rhinovirus type 37 (ATCC VR-1147, Strain 151-1),	10^{-1} to 10^{-6} dilutions	Complete Inactivation	Complete Inactivation	$10^{5.75}$
		$TCID_{50}$/0.1mL	≤0.50	≤0.50	
		Log_{10} Reduction	≥5.25	≥5.25	
497410-14	Influenza A virus (ATCC VR-544, Strain Hong Kong)	10^{-1} to 10^{-6} dilutions	Complete Inactivation	Complete Inactivation	$10^{5.25}$
		$TCID_{50}$/0.1mL	≤0.50	≤0.50	
		Log_{10} Reduction	≥4.75	≥4.75	
497410-15	Herpes simplex virus type 2 (ATCC VR-734, Strain G)	10^{-1} to 10^{-8} dilutions	Complete Inactivation	Complete Inactivation	$10^{5.5}$
		$TCID_{50}$/0.1mL	≤0.50	≤0.50	
		Log_{10} Reduction	≥5.0	≥5.0	

MRID Number	Organism	Description 5 minutes	Lot No. 3483SWE105	Lot No. 3503SWB105	Lot No. 4443SWB105	Dried Virus Control
497410-16	Poliovirus type 1 (ATCC VR-1562, Strain Chat)	10^{-1} to 10^{-8} dilutions	Complete Inactivation	Complete Inactivation	Complete Inactivation	
		$TCID_{50}$/0.1mL	≤0.50	≤0.50	≤0.50	
		Log_{10} Reduction	≥5.0	≥5.0	≥5.0	

MRID Number	Organism	Lot No. 3 minutes	CFU/Carrier Average Log_{10}	Percent Reduction	Carrier Population (Log_{10} CFU/Carrier)
497410-18	*Enterobacter aerogenes* (ATCC 13048)	3483SWE105	<1.40	>99.9%	6.79
		3503SWB105	<1.40	>99.9%	
		4443SWB105	<1.40	>99.9%	
	Staphylococcus aureus (ATCC 6538)	3483SWE105	<1.40	>99.9%	7.16
		3503SWB105	<1.40	>99.9%	
		4443SWB105	<1.40	>99.9%	

VI. CONCLUSIONS

1. The submitted efficacy data (MRID 497410-07 and MRID 497410-08) support use of the product, XHC-E (EPA File Symbol 1677-ELU), as a **hard non-porous sporicide product** when tested at 5000 ppm available chlorine against *Bacillus subtilis* (ATCC 19659) and *Clostridium sporogenes* (ATCC 3584) for a 300 minutes (5 hours) contact time by immersion in the presence of 5% organic soil load.

2. The submitted efficacy data (MRID 497410-09) support use of the product, XHC-E (EPA File Symbol 1677-ELU), as a **disinfectant with sporicidal activity against *Clostridium difficile* (ATCC 43598)**, when tested at 5000 ppm available chlorine, on hard, nonporous surfaces for a 10 minutes contact time in the presence of 5% organic soil load.

3. The submitted efficacy data (MRID 497410-03) support use of the product, XHC-E (EPA File Symbol 1677-ELU), as a **disinfectant with bactericidal activity** against *Staphylococcus aureus* (ATCC 6538) and *Pseudomonas aeruginosa* (ATCC 1544), when tested at 5000 ppm available chlorine, on hard, nonporous surfaces for a 7 minutes contact time in the presence of 5% organic soil load

4. The submitted efficacy data (MRID 497410-10) support use of the product, XHC-E (EPA File Symbol 1677-ELU), as a **disinfectant with bactericidal activity** against *Escherichia coli* (ATCC 11229), when tested at 5000 ppm available chlorine, on hard, nonporous surfaces for a 5 minutes contact time in the presence of 5% organic soil load.

5. The submitted efficacy data support the use of the product, XHC-E (EPA File Symbol 1677-ELU), as a **disinfectant with fungicidal activity** against the following microorganism, when tested at 5000 ppm available chlorine on hard, nonporous surfaces for a 5 minute contact time in the presence of 5% organic soil load:

MRID 497410-04	*Trichophyton mentagrophytes* (ATCC 9533)
MRID 497410-05	*Aspergillus brasiliensis* (ATCC 16404).
MRID 497410-06	*Candida albicans* (ATCC 10231)
MRID 497410-17	*Penicillium chrysogenum* (ATCC 10003)

6. The submitted efficacy data support the use of the product, XHC-E (EPA File Symbol 1677-ELU), as a **disinfectant with virucidal activity** against the following microorganisms, when tested at 5000 ppm available chlorine on hard, nonporous surfaces for a 5 minute contact time in the presence of 5% organic soil load:

MRID 497410-11	Adenovirus type 5 (ATCC VR-5, Strain Adenoid 75)
MRID 497410-12	Herpes simplex virus type 1 (ATCC VR-733, Strain F(1))
MRID 497410-13	Rhinovirus type 37 (ATCC VR-1147, Strain 151-1)
MRID 497410-14	Influenza A virus (ATCC VR-544, Strain Hong Kong)
MRID 497410-15	Herpes simplex virus type 2 (ATCC VR-734, Strain G)
MRID 497410-16	Poliovirus type 1 (ATCC VR-1562, Strain Chat)

7. The submitted efficacy data (MRID 497410-18) support use of the product, XHC-E (EPA File Symbol 1677-ELU), as a **sanitizer** against *Staphylococcus aureus* (ATCC 6538) and *Enterobacter aerogenes* (ATCC 13048), when tested at 5000 ppm available chlorine, on hard, nonporous surfaces for a 3 minutes contact time in the presence of 5% organic soil load.

VII. LABEL

1. The proposed label claims that the product, XHC-E (EPA File Symbol 1677-ELU), is a **sterilant**, when used undiluted, at room temperature, for 300 minutes (5 hours) **are not supported** by the applicant's data. Registrant did not submit data for porous surfaces. **All sterilant claims and references must be removed and replaced with "Hard Non-Porous Surface Sporicide". The submitted data only support hard non-porous sporicidal claims. All sporicidal claims and references must be preceded by "hard non-porous surface".**

2. The proposed label claims that the product formulation, XHC-E (EPA File Symbol 1677-ELU), is a disinfectant with sporicidal activity against *Clostridium difficile* (ATCC 43598) spore, when used undiluted, on hard,

nonporous surfaces with a 10 minute contact time: **These claims are acceptable as they are supported by the submitted data. Note that registrant must always use the terms "disinfectant with sporicidal activity against *Clostridium difficile.***

3. The proposed label claims the product, XHC-E (EPA File Symbol 1677-ELU), is a disinfectant against the following bacteria, when used undiluted, on hard, nonporous surfaces, at room temperature, for a 7 minute contact time in the presence of 5% organic soil load:

Staphylococcus aureus (ATCC 6538)
Pseudomonas aeruginosa (ATCC 15442)
Escherichia coli (ATCC 11229)

These claims are acceptable as they are supported by the submitted data.

3. The proposed label claims that the product formulation, XHC-E (EPA File Symbol 1677-ELU), is a disinfectant with fungicidal activities against the following fungi, when used undiluted, on hard, nonporous surfaces, at room temperature, for a 5 minute contact time in the presence of 5% organic soil load.

*Trichophyton mentagrophytes (*ATCC 9533)
Candida albicans (ATCC 10231)
Aspergillus brasiliensis (ATCC 16404)
Penicillium chrysogenum (ATCC 10003)

These claims are acceptable as they are supported by the submitted data.

4. The proposed label claims that the product formulation, XHC-E (EPA File Symbol 1677-ELU), is a disinfectant with virucidal activities against the following viruses, when used undiluted, on hard, non-porous surfaces, at room temperature, for a 5 minute contact time in the presence of 5% organic soil load.

Herpes Simplex Type I Virus (Herpes) (ATCC VR-733)
Herpes Simplex Type II Virus (Genital Herpes) (ATCC VR-734)
Influenza A Hong Kong H3N2 Virus (ATCC VR-544)
Rhinovirus Type 37 (ATCC VR-1147)
Poliovirus 1 (ATCC VR-1562)
Adenovirus Type 5 (ATCC VR-5)

These claims are acceptable as they are supported by the submitted data. Registrant must list Adenovirus as "Adenovirus 5 (ATCC VR-5)" or "Adenovirus Type 5 (ATCC VR-5)" on the label.

5. The proposed label claims the product, XHC-E (EPA File Symbol 1677-ELU), is a sanitizer against the following bacteria, when used undiluted, on non-food, hard, non-porous surfaces, at room temperature, for a 3 minute contact time in the presence of 5% organic soil load:

Staphylococcus aureus (ATCC 6538)
Enterobacter aerogenes (ATCC 13048)

These claims are acceptable as they are supported by the submitted data.

6. The applicant must make the following changes to the proposed label ((in addition to the label changes identified in items 1, 2 and 4 above):

- On page 1, "Water for Injection" references should be qualified as a component of the disinfectant as this may be seen as liquid for perfusion.

- On page 1, replace the word "sanitizer" with "non-food contact sanitizer."

- On page 4, replace "Direction for Use as a Sterilant" and "Direction for use as a Sporicide" respectively with "**Direction for Use as a Hard Non-Porous Sporicide**" and "**Direction for Use as a Disinfectant with Sporicidal Activity Against *Clostridium difficile* Spores**".

- On page 4, revise "recommended contact time" to read "required contact time."

- On page 4, revise the statement "Remove any obvious debris or organic material from the surface to be cleaned" to read "Clean the surface to be treated of debris or organic material."